



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Dionne et al.

Serial No.: 10/814,801

Filed: March 31, 2004

For: OSMOTIC PUMP WITH MEANS
FOR DISSIPATING INTERNAL
PRESSURE

Confirmation No.: 4974

Examiner: S. Kennedy

Group Art Unit: 1615

Attorney Docket No.: 3139-6349.1US
(ALZ5018/2697)

Notice of Allowance Mailed:

November 27, 2006

NOTICE OF EXPRESS MAILING

Express Mail Mailing Label Number: EV962537496US

Date of Deposit with USPS: February 27, 2007

Person making Deposit: Di Sanders

TRANSMITTAL LETTER

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith Part B - Fee(s) Transmittal for the above-captioned application and a check in the amount of \$1,700.00 in payment therefor.

Also enclosed are Comments on Statement of Reasons for Allowance and Fee Addressee for Receipt of PTO Notices Relating to Maintenance Fees.

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Applicants understand that no additional fees are required. However, if the Office determines that any comparison fees or other additional fees are required, the Commissioner is authorized to charge any such fees to TraskBritt Deposit Account No. 20-1469. A copy of this Transmittal Letter is enclosed for deposit account charging purposes.

Respectfully submitted,



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Telephone: 801-532-1922

Date: February 26, 2007

ERC/dlm:tp

Enclosures: Part B - Issue Fee Transmittal

Check No. 23513 in the amount of \$1,700.00

Copy of Transmittal Letter

Comments on Statement of Reasons for Allowance (6 pages)

Fee Addressee for Receipt of PTO Notices Relating to Maintenance Fees (2 pages)

Document in ProLaw



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COMMENTS ON STATEMENT OF REASONS FOR ALLOWANCE

Mail Stop Issue Fee
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

This communication is filed in response to the Notice of Allowance mailed August 14, 2006 and sets forth Applicant's comments, pursuant to 37 C.F.R. §1.104(e), on the Examiner's Statement of Allowable Subject Matter accompanying the Notice of Allowance.

In the Notice of Allowance, the Examiner indicates:

New prior art is cited for consideration before the examiner. There is another International Search Report dated July 28, 2006, containing additional references considered to be "X" type references, or, considered to anticipate claimed subject matter. Whether or not this search report has been conducted in reference to claims similar to those before the examiner is irrelevant, however,

careful review of these references are necessary, paying particular attention to those passages considered pertinent by the European Examiner. The following comments are provided.

This application is directed to an osmotic pump having at least one vent formed through at least one wall defining a boundary of a reservoir. A semipermeable membrane is positioned to seal the vent, and the membrane is displaceable relative to the reservoir when a threshold pressure is reached. Claim 20 is broader in that the semipermeable membrane is broadened to a means for removably sealing the vent. This is an important aspect of the invention. The venting is seen in action in applicant's figure 4. Note that in that figure, the semipermeable membrane 22 displaced from the reservoir 12 containing drug 14. This feature is important and is discussed in detail in applicant's published paragraphs [0005] and [0006].

All of the new prior art has been studied, with particular care and detail in regard to the portions referred to in the International Search Report. The features recited in applicant's claimed subject matter are neither shown nor suggested by the new prior art. Accordingly, the claims are again allowed.

Also note previous comments from August 14, 2006 Notice of Allowance:

New prior art is cited for consideration before the examiner. In addition, there is a petition decision of July 26, 2006 which permits the application to now move forward.

Note is made of the International Search Report dated November 22, 2004 and the references cited therein. These references have been studied, particularly the passages cited, however, none of the references disclose the osmotic pump having the vent and semipermeable membrane being capable of displacement upon reaching a threshold pressure.

The patent to Carr et al., US 6,508,808, has already been discussed by the examiner in the previous office action. The patent to Dionne, US 6,132,420, was already considered by the examiner and is listed in the first PTO-1449. The patent to Harper et al., US 6,436,091, discloses an implantable osmotic device for long-term use. With reference to figure 2, Harper discloses a plurality of openings 216 covered by a semipermeable membrane 214, which is in turn covered by an impermeable barrier 220. The barrier 220 may be breached by a physician after implantation by needle 222. Note figure 3 and the various barrier configurations in sheet 2. This patent does not show a semipermeable membrane responsive to a threshold pressure in the osmotic pump as set forth in the independent claims.

The patent to Balaban et al., US 5,308,348, discloses a delivery device having osmotic agent 15, movable piston 17, drug exit orifice 91 covered by, for example, resilient band 21. The band is sufficiently tight to seal the orifice, but is capable of being stretched by the force of the moving partition 17 (transmitted

through the beneficial agent) to separate sufficiently from the orifice to permit escape of the beneficial agent. Once the force is spent, the band once again seats against the orifice, thus providing the pulsatile delivery. This patent does not show the vent as claimed. The band is not a semipermeable membrane. Further, the osmotic agent is not vented out of pump or released in anyway as required by the independent claims.

Regarding Brown et al., WO 02/43800, this reference discloses a plug 10 for use with an osmotic delivery device having an expansion control channel which accommodates the thermal expansion of a drug formulation, which may optionally contain a frit. Figure 5 shows drug entrance port 35, spiraled expansion control channel 21, frit 50 and outlet 45. Sheet 6/11 shows the assembly of the device and the compression of air 5. This reference does not show the claimed embodiments, including a semipermeable membrane responsive to a threshold pressure, in combination with the other elements.

The advantages of this device over the prior art were discussed in detail by the examiner in the previous Notice of Allowance. The remaining undiscussed cited prior art is less relevant and no comment is deemed necessary. Accordingly, this application is again allowed.

Also note previous comments from March 20, 2006 Notice of Allowance:

Applicant's claims are directed to an osmotic pump having a vent to release at least a portion of the osmotic agent. The purpose of the invention is set forth adequately in the background of the invention. It is beneficial to prevent the sudden release of a large amount of osmagent to the patient when an osmotic pump breaks in two. In addition, the venting prevents the breakage by preventing the pressure build up after the beneficial agent is released.

The patent to Ayer, US 6,270,787 is distinguished because holes 30, which at first glance could appear to be vents, function to allow the membrane plug 26 to swell into the holes creating a large frictional force between the membrane plug and the interior capsule walls which prevents membrane plug expulsion. Accordingly, holes 30 are not vents.

Regarding the patent to Theeuwes et al., US 5,312,389, port 21 is not a vent; it is the means by which syringes 20 and 60 may be filled with a beneficial agent. The agent is filled by injecting the beneficial agent through the fluid injection port 21. Theeuwes discloses vent 34, however, this is operable to vent the container 30 during filling. After attaching the container 30 to syringe 20, a liquid 40 is introduced into container 30 through port 33. Ambient pressure is maintained within container 30 by means of a vent 34 that extends through the wall of container 30. The vent 34 is filled with a material that is permeable to air but not permeable to the liquid. Accordingly, this reference does not disclose or

anticipate a vent which is operative upon displacement of a semipermeable membrane.

The patent to Trautman, 2005/0095284, which has a later provisional filing date than the instant application, shows what appears to be a vent in figure 2C. However, orifice 216 merely allows fluid to pass through the membrane plug 200 to the osmotic agent and has the effect of accelerating the startup phase of the osmotic pump. There is no venting because upon adequate hydration/swelling of the columnar body 202 the orifice 216 becomes occluded which allows the osmotic function of the system to be fully activated.

The patent to Carr et al., US 6,508,808, discloses an osmotic delivery device with a vent 32 operative to vent from clearance 34 upon movement of valve 28 to clear the opening of the delivery orifice 18. Semipermeable membrane 30 is situated at the opposite end of these features. Assuming that delivery orifice 18 could be reasonably interpreted to be a vent, then this structure is similar to applicant's claim 20. However, claim 20 requires an exposing of the osmotic agent and release of at least a portion of the osmotic agent in the reservoir. See applicant's figure 4. In contrast, the Carr osmotic agent 24 is separated from orifice 18 by piston 20.

The patent to Peterson et al, US 6,840,931, discloses a vent hole 24 which is operative to vent the reservoir during filling thereof through fill hole 22. This is also distinguished from the invention because caps 26 are applied to seal the holes. The function of the caps is described in column 18, lines 13-29. "The caps 26, or means for sealing the holes 22, 24 from the surrounding environment, may be fashioned from a material similar to that of the osmotic delivery system flow modulator body 21, and should sufficiently seal the fill hole 22 and vent hole 24 from the environment of use such that external liquids from the environment of use do not substantially leak or diffuse into the osmotic delivery system 40, and such that pressures generated from the osmotic agent 47 within the osmotic delivery system 40 do not substantially cause the beneficial agent 44 to leak out from the fill hole 22 or vent hole 24. The caps 26 may press fit or thread into the holes 22, 24."

The patent to Maruyama et al., US 5,997,902, also discloses a vent 39 which is operative to permit the escape of gases. This vent has nothing to do with the vent claimed in applicant's invention.

The patent to Magruder, US 5,234,693, also discloses vents 40a and 40b. These are fluid or fluid vapor passage means formed through the wall of the sleeve and are designed to communicate with the outside environment. They facilitate

ventilation of air from space 32 during the implant procedure and provide another point of access to second section 12b for the fluid or fluid vapor environment.

Since none of the prior art discloses or suggests the claimed invention, the application is allowed.

Applicants concur with the reasons as stated by the Examiner insofar as they comprise a summary, which is exemplary and not limiting. However, the scope of the claims is based on the actual language of the claims and equivalents thereof, and not on a paraphrase or summary of the claim language.

The Independent claims as allowed recite features and methodology in addition to, and in different language than, those described in the Statement of Allowable Subject Matter. Furthermore, the dependent claims recite elements in addition to those of the independent claims, which are also not reflected in the Statement of Allowable Subject Matter. Such additional elements, in combination with those of the independent claims from which each claim depends, provide additional reasons for patentability. Accordingly, the scope of the claims must be determined from the literal language of each as a whole, as well as all equivalents thereof.

Therefore, to the extent that the Examiner's reasons for allowance as stated are not relevant to, or wholly encompassing of, a particular claim, independent or dependent, Applicants assume that (pursuant to 37 C.F.R. §1.104(e)) the Examiner has determined that the record of the prosecution as a whole of the application makes clear the reasons for allowing those claims.

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Further, it appears, pursuant to M.P.E.P. 1302.14, that the Examiner's Statements of Allowable Subject Matter are not intended to encompass all of the reasons for allowance.

Respectfully submitted,



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